

**REMARKS**

Applicants respectfully request further examination and reconsideration in view of the arguments set forth fully below. In the Office Action mailed December 12, 2008, claims 1-20 have been rejected. In response, the Applicants have submitted the following remarks. Accordingly, claims 1-20 are still pending. Favorable reconsideration is respectfully requested in view of the remarks below.

**Rejections Under 35 U.S.C. §103**

Claim 1 has been rejected under 35 U.S.C. §103(a) as being unpatentable by U.S. Patent No. 7,069,069 to Fishler et al. (hereinafter Fishler) in view of U.S. Patent No. 5,514,164 to Mann et al. (hereinafter Mann). The Applicants respectfully disagree with this rejection.

Within the Office Action, it is stated that although the Fishler reference does not set out to only detect cardiac repolarization abnormalities, his investigation of CHF includes detecting or not detecting cardiac repolarization since CHF would cause some abnormal repolarization. The Applicants are having a difficult time understanding the Examiner's assertion in this case. Specifically, the Applicants cannot understand how the Examiner believes that Fishler actually teaches detecting cardiac repolarization at all just because CHF would cause the same. The Applicants respectfully submit that just because CHF may cause repolarization, does not mean a reference teaching the detection of CHF also teaches the detection of repolarization. In fact, the Applicants respectfully submit that CHF likely causes a number of cardiac and non-cardiac conditions. However, the detection of any or all of these conditions, cardiac or otherwise, are not taught in the Fishler reference. For example, CHF may cause a number of non-cardiac conditions such as high blood pressure or kidney failure or joint discomfort, but the detection of these ailments are not taught in the Fishler reference, and therefore the Fishler reference is not appropriate to be cited in an application that teaches detection of these ailments. The Applicants know of no precedential doctrine that allows the Examiner to make such a connection when the underlying detection of a particular condition is not taught in the reference.

Furthermore, it is widely known in the art that CHF patients do not have repolarization abnormalities related to CHF. If such patients have repolarization abnormalities they are due to other causes or the underlying disease that brought on the CHF (e.g. a scar). It is long been desired to detect the degree of CHF from the ECG, but this can not be done. In short, they are not related to one another.

Furthermore, it is stated within the Office Action that the Applicant does not disclose criticality to using an external device as opposed to an internal device, and that an internal device will work equally well at deriving the desired data from the heart. As discussed in the previous Office Action and now repeated below, there is criticality in using an external versus an internal device. In addition to this argument, it is well known in the art that any morphology between the electrogram and ECG are very different.

Again, Fishler teaches an **implantable cardiac device** and method for providing monitoring of a progression or regression in heart disease over an extended time period. The Fishler reference teaches determining morphology measurements from **an electrogram** of a patient that indicate progression or regression in heart disease (Fishler, abstract). Within the Office Action, it is stated that the Fishler reference teaches deriving a total quantity of representative beats of the at least one electrocardiogram signal, and further that Fishler teaches using the data corresponding to at least some of the total quantity of values to assess cardiac repolarization abnormality. In fact, the Fishler reference actually teaches an implantable device that detects an intra-cardiac signal called an electrogram signal (See Examiner citations), rather than the ECG that the present application is detecting from the torso of the patient. It is well-known in the art that morphology between an electrogram and an ECG are very different measurements, in that the electrogram is taken from an implantable device and no specific morphology features of repolarization are found in such a signal.

Again, the Applicants respectfully submit that this comment by the Examiner does not properly show the teachings of using data corresponding to at least some of the total quantity of values to assess cardiac repolarization abnormality. The Examiner assumes that because CHF may have abnormal cardiac repolarization, that the invention taught in Fishler would in fact be used to assess such abnormality. However, as the Applicants discussed above with

respect to the deriving step, because the implantable device of Fishler detects an intracardiac signal called an electrogram, such repolarization abnormality would not and could not be taught by Fishler.

The Examiner cites the Mann reference, column 1, lines 43-62 to show that both an ECG and an EGM provide information about repolarization. However, as described above, these signals are very different, and the Mann reference merely states that the cardiac rhythm may be recorded by an ECG or an EGM. The Mann reference does not take into account the differences in these measurements with respect to morphology between the electrogram and the ECG. Therefore, even if combined, the Fishler and Mann references do not teach the functionality of the present application.

In contrast to the teachings of Fishler, Mann, and their combination, the method and apparatus for detecting cardiac repolarization abnormality of the present invention includes focusing on repolarization morphology features and ECG, and those features time series changes. The present application uses a group of specifically defined morphology features, none of which are taught or disclosed in the prior art listed above. The method and apparatus of the present application derives a total quantity of representative beats of an at least one electrocardiogram signal taken from a patient ECG, determines a total quantity of values representing the total quantity of representative beats using the at least one morphology shape descriptor, and uses the data corresponding to at least some of the total quantity of values to assess cardiac repolarization abnormality in the patient. The Applicants respectfully submit that Fishler nor Mann teach deriving a total quantity of representative beats of the at least one electro cardiogram signal taken from a patient ECG, nor using data corresponding to at least some of the total quantity of values to assess cardiac repolarization abnormality in the patient.

The independent claim 1 is directed to a method of detecting cardiac repolarization abnormality using at least one electrocardiogram signal, the method comprising: deriving a total quantity of representative beats of the at least one electrocardiogram signal taken from a patient ECG; using at least one morphology shape descriptor to determine a total quantity of values representing the total quantity of representative beats, wherein the morphology shape descriptor utilizes any one of the following morphology features to determine the total

quantity; a maximum morphology feature; a minimum morphology feature; an area morphology feature; an amplitude morphology feature; a slope morphology feature; and a time interval morphology feature; and using data corresponding to at least some of the total quantity of values to assess cardiac repolarization abnormality in the patient. As discussed above, Fishler does not teach deriving a total quantity of representative beats of the at least one electro cardiogram signal taken from a patient ECG, nor using data corresponding to at least some of the total quantity of values to assess cardiac repolarization abnormality in the patient. For at least these reasons, the independent claim 1 is allowable over the teachings of Fishler, Mann, and their combination.

Claim 1 has been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,571,122 to Schroepell at el. (hereinafter Schroepell) in view of Mann. The Applicants respectfully disagree with this rejection.

Within the Office Action, it is first stated on page 4, lines 14-16, that the Examiner considers an abnormal heart variability is the result an abnormal cardiac repolarization. However, on page 5, lines 4 through 5 of the Office Action, the Examiner then states that abnormal heart variability would cause some abnormal repolarization. The Applicants are confused by the Examiner's assertions as, in one case, the Examiner argues that variability causes repolarization, and in the next states that variability is the result of repolarization.

Notwithstanding the above inconsistency, the Applicant respectfully submits that the argument above with respect to Fishler is appropriate and accurate here with respect to Schroepell. The Applicants respectfully submit that just because heart rate variability may cause or be caused by repolarization, does not mean that a reference teaching variability also teaches detection of repolarization. Again, the Applicant respectfully submits the following arguments from the previous Office Action response for clarification.

Schroepell teaches an implantable medical device responsive to heart rate variability analysis. (Schroepell, abstract). Again, Schroepell teaches an implantable device, and as stated previously with respect to the Fishler reference the implantable device of Schroepell detects intracardiac signals called electrograms, and morphology in an electrogram signal is much different from an ECG signal. Again, the Examiner incorrectly assumes that because an abnormal heart variability is being detected by Schroepell, that this is an indication that

the Schroepell reference utilizes data corresponding to at least some of the total quantity of values to assess cardiac repolarization abnormality in the patient. However, as stated previously, the Applicants respectfully submit that no such teaching is found in Schroepell, and in fact Schroepell is focused on change of heart rate or heart rate variability in a patient. Therefore, likened to the Fishler reference above, Schroepell nor Mann teach deriving a total quantity of representative beats of the at least one electrocardiogram signal taken from a patient ECG, nor using data corresponding to at least some of the total quantity of values to assess cardiac repolarization abnormality in the patient.

Claims 1, 3, 6, 15, 16, and 20 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,531,527 to Reinhold et al. (hereinafter Reinhold), in view of U.S. Patent No. 3,683,066 to Paine et al. (hereinafter Paine). The Applicants respectfully disagree with this rejection.

Again, as was discussed above with respect to Schroepell and Fishler, the Reinhold reference teaches an ambulatory monitoring system with real time analysis and telephone transmission, that includes sampling an ECG signal that provides a plurality of ECG signal samples, and analyzing the samples in real-time and according to predetermined criteria (Reinhold, column 4, lines 30-40, as cited by Examiner). Again, the Reinhold reference teaches measuring these collected waveforms against predetermined arrhythmia criteria (Reinhold, column 5, lines 19-21, as cited by the Examiner). In contrast to the teachings of the system and method of the present application, **the Reinhold reference focuses on QRS morphology, and not specific morphology features of repolarization.** Furthermore, Paine does not teach morphology features of repolarization either. Therefore, the Applicants respectfully submit that Reinhold and Paine also do not teach deriving a total quantity of representative beats of the at least one electrocardiogram signal taken from patient ECG, nor using data corresponding to at least some of the total quantity of values to assess cardiac repolarization abnormality in the patient. For at least these reasons, claim 1 is allowable over the teachings of Reinhold, Paine and their combination.

Claims 3, 6 and 15 are dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable over the teachings of Reinhold, Paine and their

combination. Accordingly, claims 3, 6 and 15 are also allowable as being dependent upon an allowable base claim.

Claims 16 and 20 have also been rejected as being unpatentable over Reinhold, Paine and their combination. The independent claims 16 and 21 include similar limitations to the independent claim 1, and therefore, the Applicants respectfully submit that the independent claim 16 and 20 are also allowable over Reinhold, Paine and their combination.

Claims 2 and 17 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Reinhold, in view of Paine, in view of U.S. Patent No. 5,215,098 to Steinhaus et al. (hereinafter Steinhaus). Claims 2 and 17 are dependent upon the independent claims 1 and 16, respectively. As discussed above, the independent claims 1 and 16 are allowable over the teachings of Reinhold, Paine and their combination. Accordingly, claims 2 and 17 are also allowable as being dependent upon an allowable base claim.

Claims 4-5, 7 and 11 having been rejected under 35 U.S.C. §103(a) as being unpatentable over Reinhold, in view of Paine in view of Cohen. Claims 4-5, 7 and 11 are dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable. Accordingly, claims 4-5, 7 and 11 are also allowable as being dependent upon an allowable base claim.

Claims 12-14 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Reinhold, in view of Paine, in view of Cohen, and further in view of U.S. Patent No. 6,983,183 to Thiagarajan et al. (hereinafter Thiagarajan). Claims 12-14 are dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable. Accordingly, claims 12-14 are also allowable as being dependent upon an allowable base claim.

Claims 8 and 18 have been ejected under 35 U.S.C. §103(a) as being unpatentable over Reinhold, in view of Paine, in view of U.S. Patent No. 5,713,367 to Arnold et al. (hereinafter Arnold). Claims 8 and 18 are dependent upon the independent claims 1 and 16, respectively. As discussed above, the independent claims 1 and 16 are allowable. Accordingly, claims 8 and 18 are also allowable as being dependent upon an allowable base claim.

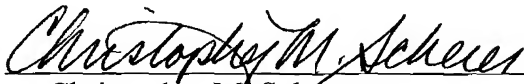
Application No. 10/825,494  
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Reply to Office Action of December 12, 2007

Claims 9-10 and 19 have been ejected under 35 U.S.C. §103(a) as being unpatentable over Reinhold, Paine and Arnold as applied to claims 8 and 18 above in view of U.S. Patent No. 6,847,840 to DePasquale et al. (hereinafter DePasquale). Claims 9-10 and 19 are dependent upon the independent claims 1 and 16. As discussed above, the independent claims 1 and 16 are allowable. Accordingly, claims 9-10 and 19 are also allowable as being dependent upon an allowable base claim.

For these reasons, Applicants respectfully submit that all of the claims are now in a condition for allowance, and allowance at an early date would be appreciated. Should the Examiner have any questions or comments, they are encouraged to call the undersigned at 414-271-7590 to discuss the same so that any outstanding issues can be expeditiously resolved.

Respectfully submitted,

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